

REMARKS

The present amendment is responsive to the Final Office Action mailed September 8, 2008. Claims 1-20 have been cancelled without prejudice or disclaimer. New claims 21-32 have been added and are consistent with the previous election of species requirement and do not introduce new matter.

Claim rejections under 35 USC 102(b) / 35 USC 102(e)

The previously pending claims were rejected under 35 USC 102 as being anticipated by Juster et al. ("Juster") or Pedersen et al. ("Pedersen"), which was cited as "3934721." Applicant presumes that this was a typographical error and that the intended reference is US 6,355,004 as cited in the PTO-892.

With respect to the pending claims, Juster fails to teach or suggest each and every claimed element. Accordingly, the rejection is unsupportable and must be withdrawn. For example, Juster fails to teach or suggest a distal catheter section having a fastening mechanism. The Examiner interprets arm 35 to be the distal section and this portion lacks any structure to fasten or engage an attachment mechanism of a tubular member (i.e., there is no fastening mechanism). Further, the reference fails to teach or suggest a tubular member having an attachment mechanism. The reference completely lacks any such structure as the sheath 21 (which the Examiner reads as the tubular member) is simply slid over the catheter with no other coupling. While the end of the sheath 21 may abut the arm 35 there is no attachment or fastening mechanism; nor is there any teaching or suggestion to sealing engage one to the other. Further, the explicitly stated purpose in the Juster reference is to provide ease of access with gloved hands in a surgical setting; thus, the reference would teach away from a modification to provide additional mechanical interconnection, were the Examiner to attempt to assert the same.

Similarly, Pedersen fails to teach the claimed subject matter. The Examiner interprets the proximal section to be the catheter 1 and the distal section to be the conical connector member 3. There is no teaching of providing a fastening mechanism on the conical connector member 3. The Examiner interprets the tubular member to be hose member 4. There is no interconnection between the hose member 4 and the conical connector member 3 nor does hose member 4

include an attachment mechanism that would engage a fastening mechanism on a distal portion of the catheter (connector 3). Were the Examiner to interpret handle 9 in combination with hose member 4 as the tubular member, there is still no interconnection with the conical connector member 3; nor is there either a fastening mechanism or an attachment mechanism. Similarly, were the Examiner to further include handle 10 with handle 9 and hose member 4 (to define the tubular member), then the entirety of the catheter assembly (connector 3, catheter 1) is fully contained within the defined "tube" (hose 4, handle 9 and handle 10) which is closed by cap 11. Accordingly, there is still no fastening of a distal end of a tubular member with a fastening mechanism at a proximal end of the distal catheter section. That is, including handle 10 causes the distal end to equate to the position at cap 11, thus failing to meet the claim limitation. Accordingly, the rejections are unsupportable and must be withdrawn.

Improper Finality of Previous Office Action

The finality of the previous office action was improper. Namely, the '004 reference is the same as WO 2000/30575, which was relied upon by the Examiner in the Office Action of August 15, 2006. In the subsequent office action dated April 9, 2007, this ground of rejection was withdrawn by the Examiner and Applicant's arguments and amendments were "deemed moot" in view of a new ground of rejection with the notable absence of any rejection based upon WO 2000/30575. Both this reference and US 6,355,004 contain the same subject matter and disclosure; there is no teaching in the now cited '004 reference that is relied upon by the Examiner that is absent from the WO 2000/30575; further, filing or priority dates are not at issue which would preclude one document or the other from being used as a reference. Thus, reinserting a previously withdrawn rejection that is in no way prompted or necessitated by Applicant's claim amendments precludes making such an action final. Applicant recognizes that the Examiner is entitled to reconsider a reference and formulate a rejection based upon that reference; however, to do so *sua sponte* precludes finality in these circumstances.

Rejections and Objections under 35 USC 112 / 35 USC 132(a)

The Examiner has objected to a previous amendment to the specification as purportedly adding new matter and certain claims were correspondingly rejected under 35 USC 112, first paragraph. Applicant respectfully traverses.

The Examiner asserts that the subject matter is not supported by “the original disclosure in conjunction with Figs 12 and 13” and that the Examiner cannot “tell that the end is closed.” Applicant respectfully asserts that the amendment to the specification is entirely consistent with the disclosure and does not introduce new matter.

It would appear that the Examiner is basing this argument in principal on the election of species requirement and the election of the embodiment referred to in Figures 12 and 13 (e.g., sections are fixed relative to one another as opposed to telescoping – the *only* differentiating feature articulated by the Examiner in support of the election of species requirement). While such a requirement mandates that the Applicant *elect claims that are generic or directed to a subset of the articulated features*, this does not segment the application into discrete, isolated blocks of text that are then considered in isolation from one another. The purpose of an election of species requirement is to restrict *claims* for the purpose of selection for examination (MPEP 809.02(a)) and not to define or limit Applicant’s specification.

II. IT IS IMPROPER TO IMPORT CLAIM LIMITATIONS FROM THE SPECIFICATION

"Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment); *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) ("Interpretation of descriptive statements in a patent's written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims 'in view of the specification' without unnecessarily importing limitations from the specification into the claims."); *Altiris Inc. v. Symantec Corp.*, 318

F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order). See also paragraph **IV.*, below. ****>When< an element is claimed using language falling under the scope of 35 U.S.C. 112, 6th paragraph (often broadly referred to as means or step plus function language)****, the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see MPEP § 2181- § 2186). MPEP 2111.01

The description provided in the specification is directed to exemplary embodiments – not limiting embodiments. Claims are provided to define the invention; not “assigned” paragraphs in a specification. The entirety of the specification and any aspect therein is available to support each and every claim and claim element, regardless of a proffered election of species requirement. Thus, while certain features (such as the telescoping coupling) are excluded *from consideration in the claims* at this time, other features are overlapping between embodiments and provide relevant teaching and support throughout the specification. That is, the various embodiments are not necessarily mutually exclusive nor does the text describing such embodiments constitute the whole of Applicant’s disclosure.

For example, a large portion of the disclosure (e.g., pages 2-9) provides description and support for various features that are generic to and/or overlapping with the various exemplary embodiments later described with reference to the figures. Thus, despite the Examiner’s assertion to the contrary, one of ordinary skill in the art would not credibly assert that the tubular member illustrated in Figures 12 and 13 is anything other than closed at the relevant end (opposite the opening).

In order to allow the annular cavity to be used e.g., for carrying a frictional reducing substance, e.g., a water or saline solution for a hydrophilic catheter, a hydrogel or similar lubricating substance, the kit may preferably be provided with a sealing engagement between the tubular protective member and the first catheter section when the tubular protect member is engaging the first catheter section. When the tubular protect member is disengaged from the first catheter section, i.e., after the catheter has reached its “read for insertion stat”, the the [sic] annular cavity is open to the ambient atmosphere thus exposing the insertable tip of the first catheter section and allowing the user to drain surplus friction reducing substances. Page 3, lines 19 – 27.

The quoted text provides one example of a generalized description that is not limited to particular embodiments and supports a tubular member that contains fluid – i.e., is closed. Thus, to add text to the specification with respect to Figures 12 and 13 only reiterates that which was previously stated in the specification, both explicitly and inherently. Finally, the claim language is interpreted in light of the specification as a whole; not selected, isolated passages. Thus, even if there were some basis to preclude Applicant from restating that which has already been described earlier in the specification; *there is absolutely no legal basis or support for the Examiner to reject corresponding claims as containing new matter unless such material is explicitly and solely limited to a literal description of Figures 12 and 13.* Such would obviate the concept of a generic or subgeneric claim and would introduce a ridiculous mandate to repeat each and every description of every possible alternative function, element, component, and every cascading combination thereof with respect to each and every figure presented. Similarly, the Examiner has proffered a new matter rejection for material that is explicitly provided in the disclosure, which is inconsistent with 35 USC 112, first paragraph which mandates that claim limitations be supported by the original disclosure; not some subset thereof.

That is, any and all subject matter disclosed by Applicant and supported by the specification may be fully and freely claimed in any combination with the only caveat being that claims must either be generic or *directed* to the elected species which is guided by reference to the drawings – not limited exclusively thereto. Ultimately, it is the Examiner's responsibility to identify the species, articulate reasons why the species are independent or distinct, and establish some indication of burden.

B) Clearly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, *to which claims are >to be< restricted.* The species are ***preferably*** identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, respectively. In the absence of distinct figures or examples to identify the several species, ***the mechanical means, the particular material, or other distinguishing characteristic of the species should be stated*** for each species identified. If the species *cannot be conveniently identified, the claims may be grouped* in accordance with the species to which they are restricted. Provide reasons why the species are independent or distinct. (Emphasis Added). MPEP 809.02(a)(B)

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Use of the Figures is a convenient tool to help *select claims for examination*; not an exclusive mandate which provides any further limitation beyond that selection. If the Examiner believes that the claims as previously amended or as presented herein are directed to a non-elected species then a proper objection to that effect may be raised; however, that is not the case and the claims are in fact directed to appropriate subject matter. Accordingly, Applicant respectfully traverses the objection and rejection and requests withdrawal of the same.

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CONCLUSION

Applicant respectfully asserts that the pending claims are in condition for allowance and notice of the same is respectfully requested. Should any issues remain outstanding, the Examiner is respectfully urged to telephone the undersigned. No additional fee are believed due at this time; however, the office is authorized to charge any fees actually due and credit any overpayment to deposit account 50-4439.

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Respectfully submitted,
Tanghoj et al.

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